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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,259	03/12/2004	Min-Hsiung Lee	0698-0177P	5872

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BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER	
WARE, DEBORAH K	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 08/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/798,259	LEE, MIN-HSIUNG	
	Examiner	Art Unit	
	Deborah K. Ware	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 April 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-8 are presented for reconsideration on the merits.

Response to Amendment

Applicants' amendment and claim to small entity filed April 15, 2005, have been received and entered. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stanley et al in view of Odell, both cited record and **newly cited** admitted prior art, note the instantly filed specification, page 3 of 19, see first full paragraph, lines 1-5.

Claims are drawn to a process for preparing lysozyme.

Stanley et al teach a process of preparing an enzyme comprising mixing a starting material with diatomaceous earth, see columns 1-2, bridging lines 65-69 and 5-7, respectively. Also treatment with a salt solution is disclosed, see column 5, lines 40-42. The salt is sodium chloride solution. Lysozyme is an enzyme which can be prepared, note column 4, line 18.

Odell teaches that egg whites is a source for lysozyme and note Table 1, column 3, lines 21-23. Further, disclosed are purification techniques such as crystallization and resin techniques such as chromatographic separation, note column 2, lines 40-47.

Newly cited admitted prior art teaches a method for purifying lysozyme by using an adsorbent such as bentonite which has the property of adsorbing lysozyme, but was not eluted. See lines 1-5, of page 3 of instantly filed specification.

The claims differ from Stanley et al in that egg whites (lyzozyme source) and specific techniques and use of naturally occurring oxides are not disclosed as being useful for adsorbing lysozyme.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use as the lysozyme source in Stanley the egg whites of Odell and further upon treating with diatomaceious earth mixtures and treatment with sodium chloride solutions (i.e. elution step) as disclosed by Stanley to purify the enzyme using crystallization or resin treatment as further disclosed by Odell in order to prepare lysozyme by adsorbing lysozyme using the diamotaceous earth disclosed by admitted prior art. Stanley et al (also referred to as Stanley herein) clearly teach that lysozyme is

a desired enzyme to prepare and to start with egg whites as a starting material in a method for preparing it is clearly an obvious modification.

One of skill would have been motivated to use egg whites because they contain lysozyme. Bentonite and diamatoceous earth as disclosed by the cited prior art combination are well known naturally occurring oxides and would have been expected to have equivalent function for absorbing the lysozyme onto the support. Furthermore, elution of the enzyme would have been expected to be successful using a salt solution because the positive charge would have been expected to attract the diatomaceous earth material. Each of the stpes of using a salt solution, crystallization, purifying with resin, adsorbtion with diatomaceious earth material and elution are disclosed. To recover unadsorbed egg solution would have been an obvious modification of the cited prior art. Thus, expected successful results would have been obtainable and the claims are obvious over the newly applied cited prior art rejection.

Response to Arguments

Applicant's arguments filed April 15, 2005, have been fully considered but they are not persuasive. The argument that the adsorption and elution steps are not disclosed is noted, however, the admitted prior art clearly teaches adsorbing the enzyme with a naturally occurring oxide of which is a functional equivalent to diatomaceous earth and thus, this step is well known and obvious; and further to elute with salt solutions is a well known step and the art teaches using a salt solution of which would have been expected to provide successful results for an elution step if one of skill in the art would have desired to elute the enzyme. The elution step, is at least

suggested, if not taught by the cited prior art. Furthermore, in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Therefore, the claims are prima facie obvious over the newly applied art rejection.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

All claims fail to be patentably distinguishable over the state of the art discussed above. Therefore, the claims are properly rejected.

The remaining references listed on the enclosed PTO-892 and/or PTO-1449 are cited to further show the state of the art.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is 571-272-0924. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Deborah K. Ware
July 23, 2005

DAVID M. NAFF
PRIMARY EXAMINER
ART UNIT 1651